

AXIOM MEDICAL, INC.

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K965146

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In compliance with the requirements of section 510(k) of the Food, Drug, and Cosmetic Act as amended, and 21 CFR Section 807.92(a)(1), This "510(k) Summary" is on a product we intends to market in 90 days.

Company name : Axiom Medical Inc.

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Contact person : Ridwan Hardy

Date of Submission: 12/20/1996

1.0 DEVICE NAMES

- 1.1 Trade Name: Axiom Closed Wound Drain With Trocar
- 1.2 Common Name: Closed Wound Vacuum Drainage Apparatus
- 1.3 Classification Name: Suction and Drainage Apparatus and Accessories, single patient use, Nonpowered
(per 21 CFR section 878.4680)

2.0 PRODUCT DESCRIPTION

This Axiom Closed Wound Drain with Trocar is simplicity of design assures effective operation with added convenience. The sterile single-patient-use component includes the following:

- 2.1 Radiopaque silicone flat drain with multiple perforations. These perforations are located at the end of the drain. Unique interlocking supports run the full length of the flat drain to maintain ample lumen and ensure unhindered flow. Various sizes starting from 4 mm up to 13 mm for flat drain with Trocars will be offered.
- 2.2 Silicone round drain with radiopaque line that allows assessment of drain placement after wound closure. An evenly spaced perforations are created to enhance drainage from several directions, these perforations are positioned in alternate 90 degree planes. Various sizes starting from 7 French up to 19 French gauge with Trocars will be offered.
- 2.3 Trocar are manufactured from stainless steel. The one end of the trocar is razor sharp to able to make a stab wound with less trauma and the opposite end has barb type fitting or beads blasted surface on small size trocars for silicone wound drain attachment. Trocars will be offered in different length and various matching diameters to silicone wound drain.

3.0 SUBSTANTIAL EQUIVALENCE COMPARISON

This device is substantially equivalent in design, indications for use and sterility to silicone flat and round wound drain system marketed by Davol, Johnson & Johnson and Baxter. These companies offer silicone wound drains system with or without trocars.

4.0 INTENDED USE OF THE DEVICE

Typical applications include:

- To drainage excessive body fluid away from the wound site in the Surgery or after Surgery